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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,914	08/10/2001	Timothy P. Tully	1314.2004-001	5180

21005 7590 03/05/2004

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EXAMINER

CRIARES, THEODORE J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/927,914	<b>Applicant(s)</b> TULLY ET AL.	
	<b>Examiner</b> Theodore J. Criares	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-106 is/are pending in the application.
- 4a) Of the above claim(s) 2, 10, 12, 13, 21, 22, 24-28, 59 and 65-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 11, 14-20, 23, 49-58, 60-64 and 94-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **CLAIMS 1--106 ARE PRESENTED FOR EXAMINATION**

Applicant's arguments filed November 10, 2003 have been fully considered but they are not persuasive.

Applicants' argument that an undue burden in the search of this application is not persuasive in view of the various cognitive disorders to be treated and the number of augmenting agents taught by applicants at page 18-21.

Applicants argue that none of the cited references alone or in combination, would have suggested the claimed invention to one of ordinary skill in the art at the time the invention was made with a reasonable expectation of success. Further, the applicants argue that none of the cited references alone or in combination, would have suggested the claimed invention, at the time the invention was made, to one of ordinary skill in the art with a reasonable expectation of success, as to the treatment of a cognitive deficit associated with stroke by using applicant's augmented cognitive treating method. And that the **pathway which effect CREB function** would be affected by the claimed therapy was not suggested by the combination of cited references.

However, it was well known in the art that in the treatment of stroke, rehabilitation of the individual suffering from a stroke should begin therapy as early as possible, even when the patient is on intravenous medication. The Merck Manual is cited as extrinsic evidence of the ordinary protocol in treating a stroke patient as will be discussed hereinafter..

It is to be noted that applicant argues the affect on a PDI on CREB function. It is well known in Patent Law that if applicants are claiming a biological pathway as the

basis for their invention then a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Therefore, the teachings in Takayama et al. and Katzung that phosphodiesterase inhibitors are useful in the treatment of stroke and the extrinsic teachings in Merck that it is well known in the art to treat a stroke victim early clearly obviates applicants claims. As the claims are drafted the patient is an individual suffering from a stroke. Such a patient would be on medication as soon as possible and be given therapy as early as possible. The rejection of May 7, 2003 is deemed proper and repeated herein.

It is deemed that applicants claims 1, 3-8, 11, 14-20, 23, 49-58, 60-64 and 94-106 will fall or be allowable if the rejections set forth herein made final or are overcome since there is a lack of criticality set forth in the specification as to the time of administration of applicants active agent, the mode of administration or the number of times the agent is administered.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-8, 11, 14-20, 23, 49-58, 60-64 and 94-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christensen. IV et al. (5,547,979 in view of Merck Manual.

Applicants elected phosphodiesterase inhibitors as the augmenting agent pspecies and shock as the disorder species. At page 18, lines 21-29 of the specification and specifically line 27 thereof the phosphodiesterase referred to therein as an augmenting agent is rolipran. Christensen IV et al. teach this compound at column 11 line 14 to column 12, line 14 and in claim 1, claim this compound in a method of treating stroke. The difference between this reference and applicants' claims, as elected and searched is the administration of the claimed known compound in conjunction with a training protocol. However, the skilled artisan would have been motivated to administer this anti-shock medication in conjunction with a training protocol since Merck Manual at pages 1455 and 1456 teach that a training protocol should be started as early as possible towards a patients rehabilitation. It is stated therein:

"Passive exercise, particularly of paralyzed limbs, and breathing exercises, if possible, should be started early."

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness. is presented.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim s 97 and 106 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds rolipram and iso-buto-metho-xanthine, does not reasonably provide enablement for "a phosphodiesterase as an augmenting agent" the generic language of claim 97 and 106. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants' specification merely cites the two compounds set forth above as having the effect of treating stroke.

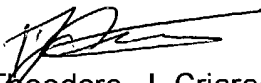
None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

TJC  
3/3/04